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(54) Title of the Invention: BALLOON AND BALLOON CATHETER

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SPECIFICATION

1. Title of the Invention

BALLOON AND BALLOON CATHETER

2. Claims

(1) A balloon in which the internal capacity can increase or decrease following the introduction and removal of a drive fluid, characterized in that it is composed of a thin member having at least an inner layer composed of a crystalline plastic and an outer layer composed of an elastic material having blood compatibility.

(2) The balloon as described in Claim 1, wherein said elastic material having blood compatibility is an antithrombotic polymer that has a microphase separated structure.

(3) The balloon as described in Claim 2, wherein said antithrombotic polymer that has a microphase separated structure is a segmented polyurethane or segmented polyamide.

(4) The balloon as described in any of Claims 1 through 3, wherein said crystalline plastic is subjected to stretching.

(5) The balloon as described in any of Claims 1 through 4, wherein the thickness of said thin member is 30-100 μm.

(6) A balloon catheter characterized in that it comprises at least a tubular body having a lumen inside thereof and the balloon described in any of Claims 1 through 5 and which is linked to said lumen.

(7) The balloon catheter as described in Claim 6, wherein said balloon catheter comprises a core inserted into said lumen, the distal end portion of said balloon is secured to the distal end portion of said core, and the base end portion of said balloon is secured to the distal end portion of said tubular body.

(8) The balloon catheter as described in claim 7, wherein said core is a tubular core having a lumen inside thereof.

3. Detailed Description of the Invention

<Field of Industrial Utilization>

The present invention relates to a balloon catheter such as an intraaortic balloon catheter, which is used, for example, to assist coronary function, and to a balloon used in such a balloon catheter.

<Prior Art Technology>

In recent years IABP (intraaortic balloon pumping) has been used on a gradually increasing scale as a means to assist circulation against the decrease in left-heart function caused by acute myocardial infarction, extracorporeal circulation detachment difficulty, heart failure after heart surgery, and low cardiac output syndrome.

The conventional IABP usually used a surgical insertion method in which the catheter was inserted into the exposed blood vessel. However, in recent years, an IABP that could be inserted through the skin was suggested. The development of an IABP for percutaneous insertion made it possible to insert the IABP easily and rapidly, not only in surgical procedures but also in internal medicine, anesthesia, and the like. As a result, examples appeared of using the IABP for prophylactics and a trend to expand the use thereof has been observed in recent years.

However, although the application range of IABP has been expanding, there are complications that cause problems. Those complications include cardiac failure, complications of blood vessel system, and ischemia. The occurrence thereof cannot be attributed only to the patients and is apparently caused by medical effects associated with the type of catheter, insertion method, and expansion method.

A balloon catheter for such an IABP was disclosed, for example, in US Patent 4,327, 709. This balloon catheter has a structure in which the base end portion of the balloon is secured to the distal end of the catheter, and the distal end of the balloon is secured to the distal end of a rigid wire inserted into the catheter.

When the balloon catheter is inserted, the balloon is shrunk and wrapped around the wire, assuming a wrapped state.

As a result, the diameter of the balloon-attached portion is decreased, and it can be inserted percutaneously, for example, by using a percutaneous catheter method.

However, in order to obtain an effective blood pumping function by expansion and contraction of the balloon in the intraaortic balloon catheter, the balloon is required to be flexible, that is, to have the prescribed compliance. Furthermore, the balloon is also required to have a sufficient strength and endurance in order to avoid the damage or rupturing of the balloon during insertion or pumping. For this purpose, the balloon has been composed on a thin member consisting of polyolefins, polyesters, thermoplastic elastomers, or the like. In order to obtain sufficient strength, the thickness of this member was about 130-150 μm or more.

However, with balloons of such a thickness, wrapping becomes difficult. Moreover, a significant reduction in the diameter of the balloon-attached portion during wrapping cannot be expected. For example, when percutaneous insertion of a balloon catheter is conducted using a sheath by Seldinger's method, if the diameter of the balloon attached portion is large, it becomes necessary to use a sheath with an accordingly large inner diameter. However, if the diameter of the sheath is increased, complications easily occur, for example, due to lower limb ischemia or the like. In addition, the load on a patient is also increased.

Moreover, if the diameter of the balloon-attached portion is large, there is a risk of the balloon being ruptured during insertion into or removal from the blood vessel because of the relation with the inner diameter of the sheath.

In addition, the conventional balloons, because of constituent materials thereof, had insufficient blood compatibility and when they were inserted for a long period, thrombocytes could adhere to the balloon. In this case, the thrombocytes that have adhered to the balloon could be separated from the balloon under the effect of balloon expansion and contraction, and the separated thrombocytes could cause lower limb ischemia and be the cause for complications.

<Problems Addressed by the Present Invention>

The present invention was developed to resolve the above-described problems of the conventional technology, and it is an object of the present invention to provide a balloon and a balloon catheter that can have reduced thickness and excellent blood compatibility, while guaranteeing sufficient flexibility, strength, and endurance of the balloon.

<Means to Resolve the Problems>

The aforesaid object is attained by the present invention described in the following clauses (1)-(8).

(1) A balloon in which the internal capacity can increase or decrease following introduction and removal of a drive fluid, characterized in that it is composed of a thin member having an inner layer composed of a crystalline plastic and an outer layer composed of an elastic material having blood compatibility.

(2) The balloon as described in clause (1), wherein said elastic material having blood compatibility is an antithrombotic polymer that has a microphase separated structure.

(3) The balloon as described in clause (2), wherein said antithrombotic polymer that has a microphase separated structure is a segmented polyurethane or segmented polyamide.

(4) The balloon as described in any of clauses (1) through (3), wherein said crystalline plastic is subjected to stretching.

(5) The balloon as described in any of clauses (1) through (4), wherein the thickness of said thin member is 30-100 μm.

(6) A balloon catheter characterized in that it comprises at least a tubular body having a lumen inside thereof and the balloon described in any of clauses (1) through (5) and which is linked to said lumen.

(7) The balloon catheter as described in clause (6), wherein said balloon catheter comprises a core inserted into said lumen, the distal end portion of said balloon is secured to the distal end portion of said core, and the base end portion of said balloon is secured to the distal end portion of said tubular body.

(8) The balloon catheter as described in clause (7), wherein said core is a tubular core having a lumen inside thereof.

<Operation>

In accordance with the present invention, the balloon is composed of a thin member comprising at least an inner layer consisting of a crystalline plastic and an outer layer consisting of an elastic material having blood compatibility. Therefore, even though the thickness thereof is less than that of conventional balloons, a sufficient strength and flexibility (compliance) can be obtained. Moreover, the balloon has excellent endurance.

As a result, in balloon catheters, and in intraaortic balloon catheters, in particular, wrapping of the balloon can be conducted in an easy manner. Moreover, the outer diameter of the balloon-attached portion in a wrapped state can be reduced.

Further, because the outer diameter of the balloon-attached portion is reduced, the percutaneous insertion of the balloon catheter is facilitated. Moreover, the inner diameter of the sheath serving as an insertion tool can be also decreased. As a result, load on the patient can be reduced, ischemia associated with a large inner diameter of the sheath can be prevented, and the occurrence of complications can be avoided.

Furthermore, because the outer sheath of the balloon is composed of an antithrombotic elastic material having blood compatibility, adhesion of thrombocytes to the balloon is avoided even in a long-term continuous usage, ischemia caused by thrombocytes separated from the balloon can be prevented, and the occurrence of complications is avoided.

<Structure of the Invention>

The balloon and balloon catheter in accordance with the present invention will be described hereinbelow based on the preferred embodiments thereof illustrated by the appended drawings.

FIG. 1 is a partial longitudinal sectional view illustrating an example of the configuration relating to the case in which the balloon catheter in accordance with the present invention is employed in an intraaortic balloon catheter.

As shown in the figures, an intraaortic balloon catheter 1 (also simply called a balloon catheter hereinbelow) is composed of a tubular body 2, a balloon 3 in accordance with the present invention, a core 4, and a branched hub 10.

This balloon catheter is described below more specifically. Thus, the balloon catheter 1 with the structure shown FIG. 1, comprises the tubular body 2 and the core 4, which passes inside a lumen 9 formed in the tubular body 2 and has a distal end portion of balloon 3 fixed to the distal end thereof. The tubular body hub 6 is fixed to the base end portion of the tubular body 2. A core hub 7 is fixed to the base end portion of the core 4. The branched hub 10 is composed of the tubular body hub 6 and the core hub 7. Furthermore, a distal end member 5 is attached to the distal end of the core 4. The distal end portion of the balloon 3 is fixed to the distal end member 5, and the base end portion of the balloon 3 is fixed to the distal end portion of the tubular body 2.

It is preferred that a material with certain elasticity be used for the tubular body 2. Examples of structural materials include thermoplastic resins such as polyolefins (e.g. polyethylene, polypropylene, ethylene–propylene copolymer, and ethylene–vinyl acetate copolymer), polyvinyl chloride, polyamide elastomers, and polyurethanes, silicone rubber, latex rubber, and the like. Among those materials, the above-mentioned thermoplastic resins are preferred, and polyolefins are especially preferred.

Examples of materials suitable for the core 4 include stainless steel (preferably high-tensile stainless steel for springs), piano wire (preferably piano wire plated with nickel or chromium), or superelastic alloys.

It is preferred that superelastic metal materials such as Ti - Ni alloys with an Ni content ratio of 49 to 58 at.%, Cu - Zn alloys with a Zn content ratio of 38.5 to 41.5 wt.%, Cu – Zn - X alloys (X = Be, Si, Sn, Al, and Ga) with an X content ratio of 1 to 10 wt.%, and Ni – Al alloys with an Al content ratio of 36-38 at.% be used as the superelastic alloys. Especially preferred among them are the aforesaid Ti – Ni alloys.

Further, a reinforcing member (not shown in the figures) may be provided at the portion protruding from the distal end of the tubular body 2 of the core 4 (this portion will be referred to hereinbelow as a protruding portion) with the object of preventing the core 4 from bending. A coil spirally wound around the outer periphery of the core 4 can be used as the reinforcing member. It is preferred that a metal material with the aforesaid formability be used as the structural material therefore.

The distal end member 5 fixed to the distal end of the core 4 functions as an induction portion of the balloon catheter 1. Furthermore, it is provided so that the distal end portion of the balloon catheter 1 causes no damage of the walls of blood vessels during insertion into the blood vessels. Accordingly, the distal end of the distal end member 5 is a hemisphere and has a curved shape.

It is preferred that a material with certain elasticity be used for the distal end member 5. Examples of structural materials include thermoplastic resins such as polyolefins (e.g. polyethylene, polypropylene, ethylene–propylene copolymer, and ethylene–vinyl acetate copolymer), polyvinyl chloride, polyamide elastomers, and polyurethanes, silicone rubber, latex rubber and the like. Among those materials, the above-mentioned thermoplastic resins are preferred.

Furthermore, it is preferred that the distal end member 5 has excellent adhesion to the below-described balloon 3.

Because the distal end member 5 also represents the distal end portion of balloon catheter 1, it is preferred that the position thereof be easily detectable by X ray observations. For this purpose, a metal member composed of a Pt or Pt alloy, W or a W alloy, Ag or a Ag alloy may be embedded in the distal end member 5, or a metal powder may be admixed thereto.

The balloon 3 in accordance with the present invention is a balloon that can be expanded (volume thereof is enlarged) or contracted (volume thereof is reduced) under the effect of changes in the internal pressure and is in the form of a tube (structural example shown in FIG. 1) with one end open and another end closed, or in the form of a tube in which both ends are open (structural example shown in FIG. 2).

The balloon 3 is fit so as to enclose the outer periphery of the protruding portion of the core 4. Further, when the balloon catheter 1 is inserted into a blood vessel, the balloon 3 is caused to shrink and assumes a state in which it is wrapped around the outer surface of the core 4 (wrapped state).

Thus, in the balloon 3, the distal end portion thereof is fixed, for example, by adhesion or fusion to the distal end member 5 secured to the distal end of the core 4,

and the base end portion of the balloon 3 is fixed, for example, by adhesion or fusion to the distal end portion of the tubular body 2.

Furthermore, the inside of the balloon 3 is linked to the lumen 9 formed inside the tubular body 2 via a distal end opening of the tubular body 2. A drive fluid is poured into the balloon 3 via the lumen 9 or the drive fluid can be removed from inside the balloon 3.

Following such pouring or removal of the drive fluid, the balloon 3 that has been inserted to the prescribed position inside the aorta can expand or shrink, thereby pumping blood in a pulsating manner.

A gas or a liquid may be used as the drive fluid. For example, gases such as helium, CO_2 gas, and O_2 gas that are easily dissolved in blood, or liquids such as physiological solution can be used as the aforesaid fluid.

The structure and dimensions of the balloon 3 itself will be described below in greater detail.

The branched hub 10 is composed of a tubular body hub 6 and the core hub 7. The tubular body hub 6 is secured air tightly or liquid tightly to the base end portion of the tubular body 2 and has an opening 8 communicating with the lumen 9 of the tubular body 2. This opening 8 functions as an inlet-outlet opening for the drive fluid, which is employed to cause the expansion or contraction of the balloon.

Thermoplastic resins such as polycarbonates, polyamides, polysulfones, polyarylates, methacrylate–butylene–stryrene copolymers and the like can be used as the material for the tubular body hub 6.

Furthermore, the core hub 7 is secured air tightly or liquid tightly to the base end of the core 4. The core hub 7 and the tubular body hub 6 may be secured, or they may also be constructed so that the core hub 7 can be rotated, while maintaining the air tight or liquid tight state therebetween. In this case, because the core 4 also rotates following the rotation of the core hub 7, the balloon 3 can be easily wrapped around the outer periphery of core 4 during wrapping.

FIG. 2 is a partial longitudinal sectional view illustrating another structural example of the intraaortic balloon catheter in accordance with the present invention. In the balloon catheter 1' shown in the figure, the core is a tubular core 40 having a lumen 11 inside thereof. The lumen 11 is open at the distal end side and can be used as: (1) a channel for passing a guide wire, (2) a flow path for supplying necessary drugs, or (3) a means for measuring the aortic pressure.

It is preferred that a material with certain elasticity be used for the tubular core 40. Examples of structural materials include thermoplastic resins such as polyolefins (e.g. polyethylene, polypropylene, ethylene–propylene copolymer, and ethylene–vinyl acetate copolymer), polyvinyl chloride, polyamides, polyimides, polyvinylidene fluoride, ethylene–tetrafluoroethylene copolymer, polyurethanes, silicone rubber, latex rubber, and the like.

A metallic tubular body may be used as the tubular core 40. It is preferred that a stainless steel tubular body, or a superelastic alloy tubular body be used as the metal tubular body. It is especially preferred that a superelastic alloy tubular body be used. The preferred examples of superelastic metal materials such as Ti - Ni alloys with a Ni content ratio of 49 to 58 at.%, Cu - Zn alloys with a Zn content ratio of 38.5 to 41.5 wt.%, Cu – Zn - X alloys (X = Be, Si, Sn, Al, and Ga) with X content ratio of 1 to 10 wt.%, and Ni – Al alloys with an Al content ratio of 36 to 38 at.% be used as the superelastic alloys. Especially preferred among them are the aforesaid Ti – Ni alloys.

Furthermore, similarly to the above-described structure, a reinforcing member may be provided at the protruding portion of the tubular core 4.

The branched hub 10 is composed of a tubular body hub 6 and a tubular core hub 13.

The tubular core hub 13 is fixed to the rear end of the tubular core 40, and an opening 12 communicating with the lumen 11 located inside the tubular core 40 is provided at the rear end thereof. Further, the tubular core hub 13 and the tubular body hub 6 may be secured, or they may be also constructed so that the tubular core hub 13 can be rotated as described hereinabove. In this case, because the tubular core 4 also rotates following the rotation of the tubular core hub 13, the balloon 3 can be easily wrapped around the outer periphery of the tubular core 4 during wrapping.

The preferred dimensions of various parts of the above-described balloon catheter 1 and 1' are shown in Table 1.

Table 1

	For adults (mm)	For children (mm)
Total length of tubular body 2	400-600 (450-525)	200-600 (200-450)
Outer diameter of tubular body 2	2.0-4.0 (2.2-3.0)	1.0-3.0 (1.1-2.5)
Thickness of outer body 2	0.1-0.4 (0.2-0.25)	0.1-0.4 (0.15-0.25)
Total length of core 4	600-1000 (700-850)	200-700 (300-600)
Outer diameter of core 4	0.2-2.0 (0.5-1.5)	0.2-2.0 (0.5-1.5)
Total length of tubular core 40	600-1000 (750-850)	200-700 (300-600)
Outer diameter of tubular core 40	0.4-2.5 (0.5-1.2)	0.4-1.0 (0.4-0.8)
Thickness of tubular core 40	0.02-0.2 (0.05-0.1)	0.02-0.2 (0.05-0.1)

In the table, values in parentheses indicate the preferred ranges.

The structure of the balloon 3 used in the balloon catheter in accordance with the present invention will be described below.

FIG. 3 is an enlarged longitudinal sectional view illustrating the structure of balloon 3. As shown in the figure, the balloon 3 is composed of a thin member 30 obtained by laminating an inner layer 31 and an outer layer 32.

The inner layer 31 is a portion mainly responsible for the strength of balloon 3 and is composed of a crystalline plastic. The crystalline plastic as referred to herein is a crystallizable plastic with a crystallization degree of 0.2-1.

The crystallization degree of a crystalline plastic can be measured, for example, by an X-ray method, density method, IR method, nuclear magnetic resonance method, and the like.

A crystalline plastic is used for the inner layer 31 because a thin inner layer 31 with high strength can be obtained if the crystalline plastic is subjected to stretching.

Therefore, the below-described crystalline plastic element may be used as is, but it is preferred that this element be used after stretching (for example, after being subjected to stretch blow molding).

Examples of such crystalline plastics include crystalline polyesters (such as polyethylene terephthalate (PET), polybutylene terephthalate (PBT), polyethylene isophthalate and copolymers thereof), polyamides, polyethylene, polypropylene, and the like. The especially preferred among them are PET and polyamides.

The outer layer 32 is a portion mainly responsible for flexibility of the balloon 3 and is composed of an elastic material having blood compatibility. The elastic material having blood compatibility as referred to herein is an elastic material that has a high resistance to adhesion of proteins or thrombocytes when it is brought into contact with blood, this property being inherent to the material itself or being induced by the addition of an additive. Therefore, if such a material is used for the outer layer 32, coagulation of blood is hindered and damage of the inner membrane of blood vessels is prevented when the material is brought into contact with the blood vessels.

Examples of elastic materials having blood compatibility include a variety of rubbers such as silicone rubber and latex rubber, polyurethane, polyamide elastomer, polyester elastomer, polystyrene elastomers, polyolefin elastomers, and various other thermoplastic elastomers.

Furthermore, antithrombotic materials may be also used, those materials being prepared by blending an antithrombotic drug such as heparin, prostaglandin, urokinase, and alginin derivatives with the aforesaid elastic material.

Furthermore, among those elastic materials having blood compatibility, antithrombotic polymers that have a microphase-separated structure, as observed when morphology observations are conducted with an electron microscope, may be also used as the antithrombotic materials by themselves,

Examples of such antithrombotic polymers that have a microphase-separated structure include urethanes such as segmented polyurethanes and fluorine-containing segmented polyurethanes, amides such as segmented polyamides (Japanese Patent Applications No. H01-314924, H02-74357), and various ester and other block copolymers such as polyhydroxyethylmethacrylate-polystyrene block copolymer, polyesther-polyester block copolymers, and the like. Among them, from the standpoint of fatigue resistance, appropriate flexibility, and excellent antithrombotic properties, urethanes, amides, and styrenes are preferred. Furthermore, segmented polyurethanes and segmented polyamides are especially preferred. When such materials are used, the microphase-separated structure formed on the surface of the outer layer 32 demonstrates excellent antithrombotic properties (in particular, suppresses the adhesion of thrombocytes).

Further, for reference, physical properties of segmented polyurethanes are presented in Table 2 hereinbelow.

Table 2

Tensile rupture strength	350 - 500 kgf/cm^2
Tensile modulus at 100% stretching	30 - 110 kgf/cm^2
Tensile elasticity modulus	1 - 4 kgf/mm^2
Elongation at rupture	300 - 700%

Thus, because the outer layer 32 of the balloon 3 is composed of an elastic material with blood compatibility, in particular, good antithrombotic properties, the adhesion of thrombocytes to the balloon can be prevented even in long-term continuous usage of the balloon. Furthermore, because the outer layer 32 is composed of an elastic material, damage of the inner walls of blood vessels is also prevented.

Moreover, forming the balloon 3 in accordance with the present invention from a combination of the inner layer 31 composed of a crystalline plastic and the outer layer 32 composed of an elastic material having blood compatibility makes it possible to provide the balloon 3 with strength, endurance, and flexibility. As a result, the thickness of the thin member 30 can be less than that of the conventional balloons.

The preferred dimensions of various parts of the balloon 3 used in the intraaortic balloon catheter are shown in Table 3 below.

Table 3

	For adults (mm)	For children (mm)
Balloon capacity	20-40 mL	1-10 mL
Total length of the balloon	180-250 mm (200-260 mm)	60-200 mm (80-150 mm)
Maximum outer diameter during expansion	12-17 mm (15-16 mm)	4-12 mm (4-10 mm)
Thickness of the inner layer	10-90 μm (10-50 μm)	10-90 μm (10-50 μm)
Thickness of the outer layer	10-90 μm (30-70 μm)	10-90 μm (30-70 μm)
Thickness of the thin member	30-100 μm (50-80 μm)	30-100 μm (50-80 μm)

In the table, values in parentheses indicate the preferred ranges.

An example of the method for the manufacture of such balloon 3 is described below.

(1) First, the inner layer 31 is formed, for example, by a stretch blow molding, and then a melt or solution of the constituent material of the outer layer 32 is caused to adhere to the outer surface of the inner layer 31, for example, by application, spraying or dipping. The outer layer 32 is then formed by drying.

(2) The inner layer 31 and outer layer 32 are then integrally formed by a two-color molding or insert molding process.

(3) The inner layer 31 and outer layer 32 are pre-molded into a two-layer tube, and then blow molding is conducted, while stretching the tube in the lengthwise direction, to mold the layers integrally.

Thus, the balloon in accordance with the present invention can be manufactured in an easy manner. In particular, as in the manufacture of balloons of the conventional single-layer configuration, the use of wax as a mold during dipping of the solution of the constituent material of the balloon becomes unnecessary. (The inner layer 31, which is manufactured in advance, serves as a mold.) Therefore, the operations of preparing the wax and then melting it out after solidification of the solution become unnecessary, and the entire manufacturing process is simplified, and the cost is reduced.

Furthermore, the balloon in accordance with the present invention may have at least the aforesaid inner layer and outer layer. For example, a laminate comprising three or more layers including the inner layer 31 and the outer layer 32 may be also used. A laminate in which an interlayer is present between the inner layer 31 and the outer layer 32 or a laminate in which an innermost layer is provided on the inner side of the inner layer 31 (none of such laminates is shown in the figures) may be also used.

Furthermore, in the example shown in FIG. 1 and FIG. 2, the outer diameter of the balloon 3 during balloon expansion is almost constant along the longitudinal direction of the balloon, but the present invention is not limited to this configuration. Thus, configurations also may be used in which the portion with a maximum outer diameter during balloon expansion is present in the vicinity of the balloon center in the longitudinal direction, or in which the portion with a maximum outer diameter during balloon expansion is shifted from the center in the longitudinal direction of the balloon to the distal end side thereof, or in which the portion with a maximum outer diameter during balloon expansion is shifted from the center in the longitudinal direction of the balloon to the base end side thereof.

In this case, the advantage of the configuration in which the portion with a maximum outer diameter during balloon expansion is shifted from the center in the longitudinal direction of the balloon to the distal or base end side thereof, is that blood can be more reliably passed to the peripheral or central side and the additional circulation effect can be demonstrated more reliably.

Furthermore, the usage of the balloon and balloon catheter in accordance with the present invention is not limited to the intraaortic balloon catheter, and they can be also used in a balloon catheter for PTCA, microscopy inside blood vessels, catheters for various monitors, balloon catheters for thrombosis prevention, and the like.

Further, it goes without saying that the configuration of the balloon catheter in accordance with the present invention is not limited to that shown in the figures.

<Effect of the Invention>

As described hereinabove, in accordance with the present invention, the flexibility, strength, and endurance of the balloon can be sufficiently ensured and also the balloon thickness can be decreased.

As a result, when the present invention is applied to intraaortic balloon catheters, the balloon wrapping can be easily conducted. Moreover, the outer diameter of the balloon-attached portion during wrapping can be reduced. In addition, because the outer diameter of the balloon attached portion is reduced, the balloon catheter can easily penetrate thorough the skin. Also, the diameter of the sheath serving as an insertion tool can be decreased. As a result, the load on the patient can be reduced, ischemia can be prevented, and complications can be avoided.

Furthermore, because the outer layer of the balloon is composed of an elastic material having blood compatibility, in particular, antithrombotic properties, the adhesion of thrombocytes to the balloon is prevented even in a long-term continuous use thereof, ischemia caused by thrombi separated from the balloon can be prevented, and complications can be avoided.

4. Brief Description of the Drawings

FIG. 1 is a partial longitudinal sectional view illustrating an example of the structure of the balloon catheter in accordance with the present invention.

FIG. 2 is a partial longitudinal sectional view illustrating another example of the structure of the balloon catheter in accordance with the present invention.

FIG. 3 is an enlarged longitudinal sectional view of the configuration of the balloon in accordance with the present invention.

[Key]

1, 1'	BALLOON CATHETER
2	TUBULAR BODY
3	BALLOON
30	THIN MEMBER
31	INNER LAYER
32	OUTER LAYER
4	CORE
40	TUBULAR CORE
5	DISTAL END MEMBER
6	TUBULAR BODY HUB
7	CORE HUB
8	OPENING
9	LUMEN
10	BRANCHED HUB
11	LUMEN
12	OPENING
13	TUBULAR CORE HUB

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[see original for diagrams]

[see original for diagram]